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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,937	02/16/2006	Naoki Taoka	05432/100L.890-US1	1883
7278	7590	11/17/2008	EXAMINER	
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			KATAKAM, SUDHAKAR	
			ART UNIT	PAPER NUMBER
			1621	
			MAIL DATE	DELIVERY MODE
			11/17/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/524,937

**Applicant(s)**

TAOKA ET AL.

**Examiner**

Sudhakar Katakam

**Art Unit**

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 and 13-110 is/are pending in the application.
- 4a) Of the above claim(s) 3, 6, 7, 13, 15, 16, 36-50, 57-62, 69-98 and 108-110 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 8-10, 14, 17-35, 51-56, 63-68 and 99-107 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4/19/05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Restriction*

1. Applicant's Remarks/Arguments, and election group I (claims 1-68 and 99-107) and single species for the examination purpose, in the reply filed on 5<sup>th</sup> Aug 2008 is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

Claims 3, 6, 7, 13, 15-16, 36-50, 57-62, 69-98 and 108-110 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) being drawn to a non-elected invention, there being no allowable generic or linking claim. Election was made **without traverse** in the reply filed on 11<sup>th</sup> Feb 2008.

The requirement is still deemed proper and is therefore made FINAL.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 and 54-55 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (see *Vas-Cath* at page 1116).

In the instant case, the claims are directed to a method for the preparation of S- or R-enantiomer of a diol having the formula (II). As practicing the claimed invention requires selective enzymatic acylation as recited in the claim 1, and the hydrolase enzyme is selected from *Pseudomonas* sp. lipoprotein lipase, and mutants and variants thereof, a means to obtain the product by enzymatic acylation is a critical element of the claims and must be described according to the requirement of 35 USC § 112, first paragraph.

The guidelines for Written Description state "The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art" (Federal Register/Vol.66, No.4/Friday, January 5, 2001/Notices, column 1, page 1105). The guidelines also state, "[t]he claim as a whole, including all limitations found in the preamble, the transitional phrase, and the body of the claim, must be sufficiently supported to satisfy the written description requirement" (at page 1105, center column, third full paragraph). An applicant shows possession of the claimed invention by describing the claimed

Art Unit: 1621

invention with all of its limitations. *Lockwood v. American Airlines Inc.* (CA FC) 41 USPQ2d 1961 (at 1966).

The Guidelines for Written Description further state: "when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus" (Federal Register, Vol.66,No.4, Column 3, page 1106). "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction of practice...., reduction to drawings...., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus" (MPEP 2163(3)(a)(ii)).

In contrast, the instant application fails to disclose in specific terms even a single enzymatic acylation using an acylating agent. Also, in the instant case, the teachings of the specification with regard to *Pseudomonas* sp. lipoprotein, and mutants and variants thereof, are the source for the hydrolase enzyme. Beyond this, the application provides no guidance to how these mutants and variants are source for the hydrolase enzyme. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only a limited number of species within the genus.

Art Unit: 1621

Thus, claiming a method using any enzyme in enzymatic acylation using an acylating agent that achieves a result without defining what means will do is not in compliance with the written description requirement. Rather, it is attempted to preempt the future before it has arrived. With regard to the mutants and variants, failure of the application to disclose which mutants and variants are the source for hydrolase enzyme, the skilled artisan would not have viewed the disclosure as demonstrating possession of the broad scope of any enzyme, and mutants and variants of *Pseudomonas* sp. lipoprotein thereof, having the source of hydrolase enzyme as recited in the claim. Therefore, the claims are properly rejected under 35 USC 112 first paragraph, as lacking adequate written description.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

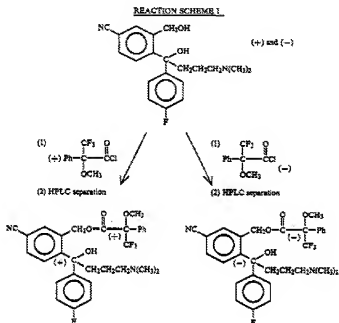
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-2, 4-5, 8-10, 14, 17-35, 51-56, 63-68 and 99-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Boegesoe et al** (US 4,943,590) in view of **Sturmer** (US 6,551,806) and **Takano et al** (US 5,219,743).

**Boegesoe et al** teach the following scheme for the preparation of S- or R-enantiomer of a diol of the following formula:



The differences between the instant claims and **Boegesoe et al** are as follows:

(i) **Boegesoe et al** fails to teach the enzymatic acylation with a hydrolase enzyme for the preparation of S- or R-enantiomer of a diol of formula (II) of claim 1.

(ii) **Boegesoe et al** fails to teach the applicants solvent for the process.

With regard to (i) of above, **Sturmer** teaches enzyme containing polymers are used as catalysts in chemical reactions such as acylation or enantioselective

Art Unit: 1621

acylation of alcohols [col.10, lines 27-35] with a preferred carboxylic acid ester as acylating agents are vinyl esters [col.12, lines 13-28]. Enzyme, such as hydrolase, preference is given to lipases from *Pseudomonas* sp. [col. 3, lines 8-65].

With regard to (ii) of above, **Takano et al** teach a method for optical resolution of corey lactone diols with an acylating agent in the presence of enzyme, such as lipase from *Pseudomonas* sp. [col.2 lines 41-68]. **Takano et al** also teach that any solvent may be used so long as it does not inactivate the enzyme and does not react with the substrate and the ester produced [col.4, lines 34-39].

In summary, **Boegesoe et al** teach the preparation of S- or R-enantiomer of a diol from its racemic mixture using enzymatic acylation with hydrolase. **Sturmer** teaches enzyme, Such as lipases, containing polymers are used as catalysts in chemical reactions such as acylation or enantioselective acylation of alcohols with a preferred carboxylic acid ester as acylating agents are vinyl esters. **Takano et al** teach that any solvent may be used so long as it does not inactivate the enzyme and does not react with the substrate and the ester produced in the process of optical resolution of corey lactone diols with an acylating agent in the presence of enzyme.

***The claims would have been obvious because, a person of ordinary skill has a good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is***



***likely the product, not of innovation, but of ordinary skill and common sense.***

***The claim would have been obvious because the design incentives or market forces provided a reason to make an adaptation, and the invention resulted from application of the prior knowledge in a predictable manner.***

***All the claimed elements were known in the prior art and one skilled person in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to have yielded predictable results to one of ordinary skill in the art at the time of the invention.***

***The Supreme Court in KSR noted that if the actual application of the technique would have been beyond the skill of one of ordinary skill in the art, then the resulting invention would have been obvious because one of ordinary skill could not have been expected to achieve it.***

In view of explicit teachings of the cited references, the examiner asserts that it would have been obvious to a person of ordinary skill in the art, at the time of invention was made, to have combined the teaching of references to make the instantly claimed process with a reasonable expectation of success. The

Art Unit: 1621

selection of acylating agent, enzyme source and the solvent is within the purview of an ordinary artisan.

Modifying such methodology is prima facie obvious because an ordinary artisan would be motivated to use known preparation methods to make the process more efficient or explore economical advantages over the other, since it is within the scope to optimize the conditions through routine experimentation. Merely modifying the process conditions such as using alternative acylating agents or enzymes or solvents, is not a patentable modification absent a showing of criticality.

### ***Conclusion***

7. No claim is allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public

Art Unit: 1621

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/Sudhakar Katakam/

Examiner, Art Unit 1621

/SHAILENDRA - KUMAR/

Primary Examiner, Art Unit 1621